UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA *ex rel.* PETER HUESEMAN, Plaintiff,	§ § §	
v.	§	CASE #: 5:14-cv-00212-XR
PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, INC., Defendant.	§ § §	

DEFENDANT'S AMENDED AND RESTATED ANSWER TO INTERVENOR'S COMPLAINT IN PARTIAL INTERVENTION

This Amended and Restated Answer is filed pursuant to the Court's Order [Doc. 152] filed on November 13, 2013, shortly after[1] Defendant, PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, INC.'S ["PCCA"] First Amended Answer [Doc. 150] asserting a statute of limitations defense pursuant to *United States ex. Rel. Aldridge v. Corp. Mgmt., Inc.*, No. 21-60568, 2023 WL 5343778, at *13 (5th Cir., Aug. 21, 2023)[hereinafter *Aldridge*] and specifically permitted by the Court via ruling from the Bench at the October 30, 2023, hearing. Those Affirmative Defenses that were stricken by the Court at the June 20, 2023, are marked as such via a ~~double strikethrough font~~. The newly permitted statute of limitations defense is denominated as PCCA's 11th Affirmative Defense. Hopefully, this format will, indeed, "best serve" the Court.

First, although the Government's Intervention supersedes the Relator Hueseman's Original Complaint, Doc. 1, and although that Complaint details many delicts against other parties that are not included in the Government's Complaint in Intervention against PCCA, as a matter of caution,

[1] PCCA apologizes to the Court for missing the November 17th deadline for filing this pleading. The Court's Order came in shortly after the Amended Answer, Doc. 150, was already on file, and counsel simply missed this deadline until Government counsel called our attention to it.

pursuant to Rule 8(b)(3), Defendant PCCA denies all allegations of the original Complaint against it. Second, PCCA generally denies each allegation, excluding any implied assertions, in the Complaint in Intervention, except those expressly admitted herein. *Id.* Finally, PCCA denies the allegations implicit in the unnumbered and bold-faced headings in the Complaint in Partial Intervention.

Subject to those qualifications and averments, PCCA responds specifically to the numbered paragraphs of the Government's Complaint in Intervention as follows:

1. PCCA specifically denies that its published AWPs were "fraudulent" or "inflated" and that its publication of those AWPs in industry compendiums was meant to induce anyone to submit a false or fraudulent claim to the Government, or that it did so. PCCA also denies that the Government paid any such claims as a proximate result of anything that PCCA did or failed to do. Subject to those qualifications, the remaining factual averments are ADMITTED.

2. ADMITTED, including information alleged in FN1.

3. ADMITTED.

4. DENIED.

5. PCCA ADMITS that its member customers did submit or present claims to various third-party insurance payers, including TRICARE, however, no claim was submitted for "PCCA ingredients" as such. All claims are, on information and belief, for the completed compound medication product. The second sentence regarding AWP is DENIED.

6. ADMITTED, including the averment in FN2.

7. Although the term "spread" is somewhat of a term of art in the Pharmaceutical Benefits (PBM) arena, PCCA admits that the difference between the amounts that its customers paid PCCA and other suppliers for ingredients and the amount that those customers received as payment for the completed compounded product was also sometimes called a "spread" but is more

accurately described as "potential profit to the pharmacies." It also admits that its customers, like most American businesses, "placed a high value" on the profit potential of their products. PCCA admits that it set both published AWP's and "actual selling prices" but denies that it had "control" over the size of the "spread" on that it "induced" its customers to file false or fraudulent claims. In fact, TRICARE and its agent ESI controlled what amount they chose to pay the PCCA customers for their compounded medications and did so with full awareness that the published "AWP" numbers for all major ingredient suppliers in this industry were not at all reflective of the pharmacies' real "acquisition prices."

8. PCCA denies that it was involved in any type of "scheme" and that its AWPs were "inflated" by any objective standard. Indeed, they were competitive with published AWPs of other suppliers within this marketplace. It admits, of course, that all published AWPs for its products, as well as its competitors, were published in industry publications. The remaining allegations of this paragraph are DENIED.

9. DENIED. Since its formation in 1981, PCCA developed and used a business model based on providing high quality products and services and, actually, customarily, and historically it charged prices that were somewhat higher than its competitors. In 2012, the market dynamics changed fairly dramatically with the introduction of D.0 and Freedom Pharmaceutical's activities that were focused on reported "AWPs" rather than on quality of products and services. When customer preferences and buying criteria changed, PCCA, of necessity, competed in the market in which it now found itself to be. PCCA's prices were very competitive. Exhibit A is a March 9, 2012 email from President Jim Smith to the Senior Management, which completes the email chain quoted by the Government. It explains that PCCA's decision that month to raise its "sticker" price, or "AWP" prices, was made to compete with "Freedom" a new "key competitor for the business of our members who bill insurance" and that the company's very legitimate capitalistic "objective

here is to give our members every reason to choose PCCA when faced with an option of using Freedom, *though our AWPs will not be higher than Freedom.*"

10. ADMITTED that, as a matter of business necessity and fair competition, PCCA's marketing and sales staff sometimes directly addressed the customers' questions about "spread." These instances were extremely limited and almost exclusively specific to an individual client's concerns or questions. *See* Answer to paragraph 9, *supra*, and Exhibit A thereto for further elaboration for benefit of the Court.

11. PCCA DENIES the sentence as written. It ADMITS that customers who achieved a certain level of purchases were initially given one on one educational support at their pharmacy, and that, when the number of customers in this category grew to too many to make that practical, PCCA sponsored educational seminars at a single location. PCCA DENIES the implication that this had anything to do with AWP's or any "spread" and that "induced" the purchases by these means. Indeed, the customers who were "rewarded" were chosen without regard to whether they had billed TRICARE or any other third party for reimbursement.

12. PCCA ADMITS that it provided consulting services to its customers following TRICARE's decision to implement NCPDP D.0 without certain regulatory definitions or guidance. PCCA denies any implication that PCCA ever submitted a claim for reimbursement. PCCA certainly ADMITS that it advised its customers, particular its "members," on how to grow their businesses, earn a profit, and get lawful reimbursement for compound prescription claims once third-party reimbursement became a reality in this country. It vehemently DENIES that it ever identified or promoted a formula for compound medications for any reason other than treatment efficacy. PCCA further alleges that any compounded pharmacy using PCCA ingredients or those from any competitor that are actually filled requires a *prescription* provided

to a pharmacy from *a physician*, whose professional obligation and legal obligation is to act in the best interest and efficacy of the patient.

13. PCCA DENIES that its pricing or promotional practices were "highly lucrative." Indeed, PCCA would show the Court that NONE of the taxpayers' money that the Government claims was paid out because of any allegedly false or fraudulent claims was paid to PCCA. It is true, of course, that the volume of compound prescriptions in this country rose dramatically in this time period, but this is a function of the fact that compounding pharmacies across the board were now able to obtain more reasonable and profitable third-party payment for such medications. The availability of these payments increased the number of compound medication prescriptions by physicians. This, in turn, increased the demand for compounding ingredients for all companies servicing this market. Therefore, PCCA's gross revenues did increase in this time period, but its profit margin on its products remained consistent with historical patterns. PCCA further DENIES the allegation or implication that PCCA's profit margin, which is based on the difference between what it had to pay bulk suppliers of its ingredients and those ingredients' sales price to the pharmacies, increased in any way because of the reimbursement amounts that the pharmacies were receiving from any third-party payor or PBM.

14. DENIED.

15. DENIED.

16. PCCA ADMITS that the United States has now intervened in this civil action originally filed by Relator Hueseman in 2014 and that it seeks monetary damages under the law. PCCA DENIES that the United States has a legitimate claims, and specifically that it can prove any violation of the Anti-Kickback Statute, the federal common law, or the following six elements required under the False Claims Act: (a) that it *caused* the submission of false or fraudulent claims by its pharmacy customers to TRICARE/ESI; (b) that claims submitted by its customers were *false*

or *fraudulent;* (c) that it acted *knowingly* within the meaning of the Act; (d) that its publication of AWP prices was truly *material* to ESI and/or TRICARE within the meaning of *Escobar* and its progeny; (e) that neither its publication of AWP prices nor its marketing practices *caused* ESI and/or TRICARE to pay the claims in the manner and amount that they did; and (f) the *quantum* of any damages attributable to PCCA or its conduct.

17. ADMITTED.

18. ADMITTED.

19. ADMITTED that PCCA is a company that has, since 1981, provided both products and services to pharmacies with regard to "compounded" medications. Those services did include both software and educational seminars about various topics, including legitimate ways to seek reimbursement or payment for their products. PCCA also provided some members (approximately 100 out of 3,000+) with an elevated level of service that included pharmacy business management and billing support.

20. ADMITTED.

21. ADMITTED.

22. ADMITTED.

23. ADMITTED.

24. ADMITTED.

25. DENIED as incomplete, overbroad and in direct conflict with *Universal Health Servs., Inc. v. United States, ex.rel. Escobar*, 579 U.S. 176 (2016)["*Escobar*"] which noted that "[t]he False Claims Act is not 'an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations" *id.* at 194 (emphasis added). Congress' purpose and intent with regard to the FCA is best expressed by the United States Supreme Court in cases like *United States v. Bornstein*, 423 U.S. 303, 312–13 (1976) which held that "[t]he Act,

in short, penalizes a person *for his own acts*, not for the acts of *someone else," id.* at 312-13 (emphasis added) and *Escobar*, itself which reminds both Bench and Bar that the congressional "focus remains on those who present or *directly induce* the submission of false or fraudulent claims." 579 U.S. at 182 (emphasis added).

26. ADMITTED.

27. ADMITTED that the quoted language appears in the cited statute, which is the section involving "criminal penalties." However, PCCA would refer the Court to the entire AKS statute, including subsection 7a pertaining to "civil monetary penalties" and also to the recent amendment to this statute. PL 117-328, 136 Stat. 4459 (December 29, 2022).

28. ADMITTED that the quoted phrase has been in the FCA since its original enactment in 1863, but with proviso (a) that the "causes to be presented" theory requires proof of "direct inducement," as the *Escobar* court wrote and that PCCA's conduct would be, at minimum, a *substantial factor* in the presentment. *See* this Court's Order, Doc. 109, regarding this element of "proximate cause."[2]

29. ADMITTED that the statute is correctly quoted, but with the caveat that the Supreme Court's opinion in *Escobar* construes this language and observes that the "materiality standard is demanding." *Id.* at 194 (emphasis added).

30. ADMITTED once again that the statute is correctly quoted, but with the caveat that the *SuperValu* case now pending in the Supreme Court will undoubtedly affect this "scienter" element substantially. *United States ex.rel. v. SuperValu, Inc.,* 143 S.Ct. 644 (2023).

31. ADMITTED.

[2] Although this Court has, to date, rejected the 8th Circuit requirement for "but for" causation, with respect PCCA maintains its position that, IF same is adopted by either the Supreme Court or the Fifth Circuit, then that is a causal requirement that the Government simply cannot meet in this case.

32. ADMITTED for the FCA. PCCA would note, however, that there is no parallel provision in the criminal statute, AKS, and that accordingly, it is not settled what burden of proof is required for the Government to prevail on that separate cause of action.

33. PCCA ADMITS that these are some of Congress' concerns, but notes that the courts' interpretation of the statute and its legislative history are more important than the Government counsel's interpretation of congressional intent.

34. PCCA ADMITS that the statutory excerpt is correctly quoted but reiterates that it applies only to products or items "for which payment may be made." PCCA's products were not "reimbursable" by TRICARE.

35. ADMITTED that the first sentence relating to punishment is an accurate description of subsection 1320a-7b(b), which pertains to *criminal* penalties. The second sentence, regarding *civil* penalties is also quoted. PCCA would further refer the Court to the entire statute which speaks for itself.

36. ADMITTED that the first sentence correctly quotes the 2010 statutory amendment of this section of the AKS. PCCA also ADMITS that, although the words "per se" do not appear in the statute, some courts have construed this language to mean exactly that. Indeed, this Court's recent opinion in this case does so. Doc. 109. Pleading further, however, with great respect, PCCA would show the Court that the law is still in flux to some degree, and that the Court and the parties will have to rely on the most recent and authoritative authorities in deciding this issue. *See, e.g., U.S. ex rel. King v. Solvay S.A.,* 823 F. Supp. 2d 472, 509 (S.D. Tex. 2011), order vacated in part on reconsideration, No. CIV.A. H-06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012).

37. PCCA admits that Government purports to rely upon a citation to the Federal Register, which does not carry the weight of law,[3] and which speaks for itself. The document cited is that of the Health & Human Services, Office of Inspector General over a decade before the allegation in this case regarding ingredient manufacturers. Therefore, PCCA is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and, therefore, denies the same.

38. ADMITTED that this section of the statute, which pertains to "criminal penalties" reads this way, but with two caveats. The first is that, because this is a criminal statute, "criminal intent" is required, even if not "specific" in the context of the statute. *See Gonzales v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 476 (5th Cir. 2012) (upholding a district court's judgment dismissing the Antikickback Statute claim due to lack of evidence that the defendant acted with criminal intent). Second, various court cases, including *SuperValu* which is now pending in the Supreme Court, may affect scienter proof in the entire FCA and AKS arena. *United States ex.rel. v. SuperValu, Inc.,* 143 S.Ct. 644 (2023).

39. ADMITTED.

40. ADMITTED.

41. First sentence regarding Provider Agreements with ESI is ADMITTED, but PCCA does not yet have copies of the Provider Agreements for the pharmacies whose claims are at issue in this case and, therefore, can neither admit nor deny the second sentence regarding ESI's Provider Manuals.

[3] By definition, guidance documents "do not have the force and effect of law." *Perez v. Mortgage Bankers Ass 'n*, 575 U.S. 92, 97 (2015) (quoting *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995)).

42. ADMITTED that PCCA's customer pharmacies were required to submit electronic data claims to ESI. However, because PCCA has not been provided with any of the actual claims "presentments," PCCA is without knowledge or information at this time to either admit or deny the remaining allegations of this paragraph. PCCA has no information that the "certain pricing information" alleged to be required includes the pharmacies' acquisition costs for the PCCA ingredients included in completed compounded prescriptions. Nor does PCCA have knowledge or information as to whether this materials' cost data was either received by ESI or utilized by ESI in adjudicating and paying claims.

43. ADMITTED that since January 1, 2012, the pharmacies were required by TRICARE and ESI to submit claims electronically in a format prescribed by D.0.

44. ADMITTED with the proviso and/or clarification that the "relevant time period" began in January 2012 when D.0 became fully effective and that "pricing information" apparently does not include the pharmacy's actual acquisition costs of the ingredients.

45. PCCA specifically DENIES that TRICARE or its agent ESI actually "reimbursed compound prescription claims" based on the "sum total of the costs submitted by the pharmacy for all ingredients in the compound drug." They were supposed to do so, and apparently claim damages based on that methodology, but, best we can tell, they did not do so. By way of explanation, PCCA would show the Court that this denial is based, in part, on the following allegation from paragraph 70 of the Relator's original Complaint [Doc.1].

> 70. . . . *Unlike U&C, pharmacy providers are not required to report their drug cost on submitted claims*, …

Because the Government has not produced its claims data, PCCA is not able to verify that it has evidence to support this allegation. If, as and when such evidence is produced, PCCA will supplement the Answer to this paragraph.

46. ADMITTED that these are some of the provisions in the ESI Provider Manual in 2013, and perhaps in earlier and later versions. The manual also shows that there are separate and distinct requirements for the submission of "compounding" claims in the manual and that TRICARE apparently had its own requirements and procedures that differed, not only from private insurers, but also from other governmentally funded agencies like Medicare. Obviously, the Manual speaks for itself.

47. ADMITTED.

48. ADMITTED that this was "generally" true, but would show the Court that non-member pharmacies did purchase ingredients from time to time, albeit at a price point that was higher than what members paid.

49. ADMITTED.

50. DENIED that pharmacies who became members of PCCA before 2007 had this requirement. ADMITTED that, for members joining after that, there was this written requirement, although in practice this provision was not firmly enforced and many PCCA members actually purchased ingredients from competitors and were not terminated.

51. ADMITTED with explanation that both "business consulting services" and "billing assistance" were offered for an additional fee. In practice, only approximately 100 of PCCA's 3000+ members actually availed themselves of these services. Moreover, "billing assistance" was mainly focused on utilization of PCCA software that enabled pharmacists, who had long lived in a world of "cash customers only/no third party reimbursement" to marshal the data that would be required for electronic submission of claims to both insurance companies and government entities like TRICARE and MEDICARE and to interface with the electronic systems used by those companies/entities or their Pharmacy Benefit Managers ["PBMs"] like ESI and provide whatever fields of data those systems required.

Preliminary Answer to All Quoted Material in Paragraphs 52-123

Paragraphs 52-123 of the Complaint in Intervention contain quotes from one of the 19 Transcripts of Sworn "Interviews" of PCCA Employees that were taken during the Civil Investigation of this case and were not made available to PCCA or its counsel until February 2023. A chart showing how comprehensive these interviews were is attached hereto as Exhibit B and incorporated herein by reference. Additionally, during the Civil Investigation PCCA produced hundreds of thousands of documents.

These paragraphs also contain quotes from portions or snippets of email chains, seminar presentations, and other documents and materials which, as FN5 reflects, were also marshaled by the Government during its seven-year investigation of this case.

The undersigned counsel for PCCA are extremely mindful of their obligations under Rule 8(b)(2) to file an Answer that "fairly responds to the substance of the allegation" and the corollary requirement of subparagraph (4) to "admit the part that is true and deny the rest." They are also acutely aware of their duty of candor to the Court and their ethical obligations under Rule 11. This Answer has been prepared with those obligations in mind.

On the other hand, our duty of zealous advocacy compels us to file a pleading that brings it to the Court's attention when an allegation tells the "truth" but not the "WHOLE TRUTH" that a witness at trial would be obligated to tell. Accordingly, PCCA admits that the quotations by Government counsel in this pleading are accurate quotations. On the other hand, where necessary, we have tried to make the "whole truth" abundantly clear in the Answer to the following paragraphs, and ask for the Court's patience and understanding in that regard.

Continuing with Answers to Numbered Paragraphs of Doc. 66

52. ADMITTED. PCCA submitted no claims to the Government and received no payments from the Government. It sold ingredients to pharmacies who compounded them into finished prescription products, filed claims with ESI, and received payment from same.

53. PCCA ADMITS that it, like all other suppliers of ingredients used in compound prescription drugs in America and, indeed, all manufacturers or suppliers of traditional medications, published "AWPs" in compendiums such as Medi-Span. PCCA also ADMITS that none of its AWPs, or, indeed, those for any suppliers are really what customers actually pay for these ingredients. PCCA DENIES the descriptive phrase "bore no rational relation." Finally, it denies the allegation of "false and fraudulent" in this paragraph.

54. ADMITTED.

55. PCCA ADMITS that it certainly knew and understood that TRICARE and ESI would have access to the AWP published prices, but DENIES that it knew to what degree they would "use" this information to "determine reimbursement" at the various applicable points in time. Indeed, what PCCA really expected regarding ESI's actions in "determining reimbursement" is that it would use commonly available cost containment tools, such a "MACs," i.e., Maximum Allowable Compensation, to control costs.

56. PCCA ADMITS that some of its customers probably viewed AWP as the likely barometer of claims payments, but did so because of the system that was created and maintained by TRICARE and its PBM Express Scripts. However, PCCA cannot admit the "proxy" allegation or the "interchangeably" allegation, but does admit that many of its customers were aware of the published AWPs for all of their ingredients, from all suppliers of same, in the context of billing and reimbursement.

57. ADMITTED.

58. PCCA DENIES the descriptor "generally" but ADMITS that there were instances when PCCA itself or some of its customers would use the word "spread" to describe the profit margin.

59. ADMITTED.

60. DENIED.

61. DENIED that this is an accurate chart.

62. DENIED.

63. ADMITTED with exception of phrase "far in excess."

64. PCCA DENIES the first two sentences and the implication of a causal connection between the first and second sentence. Pursuant to Rule 8(b)(5), PCCA, at this time, lacks the knowledge or information to admit or deny the last sentence, and would show the Court in that regard that it still has none of the actual claims submissions from the Government for those claims which the Government submits are false or with respect to which the Government is claiming damages.

65. DENIED.

66. PCCA ADMITS that the email is correctly quoted, and that Mr. Smith was genuinely concerned about customers buying "junk base" product from a competitor "solely because of reimbursement" and, accordingly, was very hesitant at that time – competition notwithstanding – to go down that pathway. None of the comments in this document pertained specifically to TRICARE.

67. PCCA ADMITS that Dr. Bassani did have those beliefs and raise those concerns. To put it into fair context, however, the entire email should be considered. The quoted comment was preceded by a statement that "our professional foundation and core values are deeply rooted

in the concept that 'lives depend on a job well done,' not in the ephemeral strategy of 'how can we create formulations with the highest AWP.'"

68. ADMITTED.

69. PCCA ADMITS the selected quotes and further admits that by March of 2012, the competitive pressures had elevated to the point that PCCA had no viable alternative if it was going to keep providing customers (and through them consumers) with its high quality products and to protect the customers' profit margins, than to increase its published "AWPs," which everyone in the industry understood to be an unrealistic "sticker" price.

70. PCCA DENIES the "concerned about scrutiny" allegation but admits that, given the complete lack of clarity from PBMs or others regarding establishment of list prices or "AWPs," Mr. Zaccardo was instructed to "use his best understanding" in setting and publishing AWP prices.

71. ADMITTED that the complete March 9, 2012, email chain, omitted as an exhibit to the Government's Complaint in Intervention but attached hereto as Exhibit A, does provide that explanation, as well as the following objective "to give our members every reason to choose PCCA when faced with an option of using Freedom, *though our AWPs will not be higher than Freedom.*"

72. ADMITTED that the prices reflected are accurate. All characterizations of them are DENIED.

73. PCCA DENIES the "across the board" phrase and the descriptive term "inflated" but otherwise ADMITS the allegations of this paragraph.

74. DENIED.

75. PCCA denies the allegation that the AWP increases were "an important part of its overall pricing and promotional strategy." Most of the quotations from sales representatives in the Government's Complaint in Intervention are from individual encounters with specific customers, and, ergo, NOT part of an "overall pricing and promotional strategy." From its formation in 1981,

PCCA competed mainly on the extremely high quality if its products and services. Thus, long before third party reimbursement became common, PCCA was actually charging prices for its ingredients that were higher than its competition. With regard to AWPs, PCCA's AWPs were typically lower than its competitors' AWPs.

76. ADMIT that the quotes from the exhibits are correct, but DENY the characterizations and implications therefrom.

77. ADMITTED.

78. ADMITTED that this was a response to a specific request from a specific customer.

79. ADMITTED.

80. DENIED.

81. ADMITTED as to the quotes. DENIED as to the characterizations.

82. ADMITTED.

83. DENIED that Mr. Zaccardo that "created" this device. Rather, it was obtained from a California worker's compensation website that is still active and periodically updated:

www.dir.ca.gov/dwc/pharmfeesched/PFScompound.asp

ADMITTED that he adopted this device in 2012, but would note that it was a static or one-shot tool, was not updated, and was not published on the PCCA website. The calculator was actually adopted in September 2012 in response to difficulties that the sales team was having in the midst of the difficult environment set up by PBS payment policies.

84. With the exception of the descriptive and pejorative phrase "already inflated," this allegation is ADMITTED.

85. ADMITTED but with the caveat that "should be" was probably more accurately stated as "what it used to be." For further explanation, hopefully of assistance to the Court and

Jury, PCCA would show that the dosages of this very toxic "nitrogen mustard" substance that were used in compounded medications were extremely small.

86. ADMITTED.

87. ADMITTED that PCCA utilized this "off the shelf" customer relationship management software product and that the isolated quotations in the following paragraphs have been excerpted from it. DENIES the "induce" implication as well as the averment that "high AWPs" were "part of the sales process.

88. ADMITTED. For clarification, the entries in the Pivotal database as produced by PCCA to the Government are voluminous. This and other quotations in the Complaint in Intervention are merely snippets from the conversation and not necessarily put in complete context individually or with regard to the entire database.

89. ADMITTED.

90. ADMITTED.

91. ADMITTED.

92. ADMITTED.

93. ADMITTED.

94. ADMITTED.

95. ADMITTED.

96. ADMITTED.

97. ADMITTED.

98. ADMITTED.

99. ADMITTED. By way of further explanation for the Court's benefit, up until the adoption of D.0 in 2012, "third party reimbursement" for compounded medications in America was very uncommon. The reimbursement amounts were amounts from insurance companies were

not typically sufficient to justify the pharmacies' pursuit of same. The advent of more widespread third-party reimbursement from insurance companies, PBMs and others, especially pursuant to D.0, certainly changed the landscape and many of PCCA's members and customers needed help, including software support, to navigate these new-to-them waters. PCCA tried its best to provide that help, to provide its customers with the best quality products and services, and, of course, to help them maximize their reimbursements and, accordingly, their profits.

100. ADMITTED.

101. ADMITTED.

102. ADMITTED that the sales representative said this, but DENIED that PCCA's published AWPs were "higher than most other competitors." The amounts of published AWPs from all suppliers of ingredients for compounding was frequently in flux.

103. ADMITTED, but with the qualification or explanation that there are many benefits of being a Diamond member.

104. ADMITTED.

105. ADMITTED.

106. ADMITTED.

107. ADMITTED.

108. ADMITTED.

109. ADMITTED.

110. ADMITTED.

111. ADMITTED.

112. With exception of the pejorative word "inflating," PCCA ADMITS this allegation.

113. ADMITTED, that PCCA sometimes held "educational seminars" and that these quotes, taken from a much larger audiotaped presentation, are accurate, albeit not in context.

114. ADMITTED with qualification and explanation that these services were available for an additional charge and only approximately 100 of PCCA's 3000+ members participated in same.

115. ADMITTED.

116. ADMITTED.

117. PCCA ADMITS the quote from the exhibit, but DENIES the accusations regarding "manipulation" and the other characterizations and allegations of this paragraph. Indeed, this software feature was added at the specific request of the Bellevue Pharmacy (previously a defendant in this case). Moreover, because the reporting of U&C was the obligation of the pharmacies, PCCA specifically cautioned users of the software to be honest and careful in their use of this automated feature. Indeed, as Mr. Klomp testified during the Civil Investigation, if a customer checked "this box for the sole reason of getting a higher reimbursement" that would not be "appropriate."

118. PCCA DENIES that it "actively monitored" TRICARE's policies but ADMITS that, once third-party reimbursement became available in the United States, that it was aware that its pharmacy customers would seek same and that it tried to help its customers enter this new age of pricing, billing, and reimbursement. It also ADMITS that the agenda and "update" document allegations are correct.

119. PCCA certainly admits the quoted allegations of this paragraph. PCCA would add that, like Ms. Ashton, Mr. Smith, and others at PCCA did not condone the billing practices some pharmacies appeared to be implementing because of the potentially destructive impact on the entire compounding industry. Although PCCA's actions were legal and permissible, this is a perfect illustration of why Mr. Smith was reluctant to compete on AWP, until it became absolutely

necessary to do so. PCCA DENIES that its revenues were tied in any direct way whatsoever to the fact that some PBM's were reimbursing based on some formula relating to AWPs.

120. ADMITTED. To put this in context, we refer the Court to the November 21, 2019 Civil Investigation testimony of PCCA's CEO David Sparks relating to this document: "I can't remember whether he did or not. I need to make this statement alongside it. The last eight to ten years of his life, he was afflicted with Alzheimer's. So you need to consider that."

121. ADMITTED.

122. DENIED because of the descriptor "highly inflated." It is certainly true that PCCA sold both of these products and that it reported AWPs for them to the industry compendia.

123. This is another instance in which, in good faith, PCCA simply lacks the knowledge or information to either admit or deny the allegation in the body of the Complaint in Intervention. *See* Rule 8(b)(5). If, as and when the Government produces the actual claims that were "presented" and the communications between TRICARE and ESI regarding these claims, PCCA will supplement or amend its Answer in this regard or confirm same via disclosures and/or discovery.

However, PCCA can respond to Exhibit 22 and does so as follows. PCCA admits that it sold certain active pharmaceutical ingredients and bases that appear on Exhibit 22 to the Government's Complaint in Partial Intervention and admits that some of the pharmacies that appear on Exhibit 22 were PCCA customers. However, the columns of information the Government included in Exhibit 22 are incomplete and not representative of all the data fields available to Government, including whether TRICARE or ESI reviewed, adjudicated and approved the amount paid for each claim and even whether the amount paid is based on AWP or some other metric. Additionally, because PCCA never submitted any claims to TRICARE or received any payments from TRICARE, PCCA lacks information and knowledge sufficient to admit or deny the accuracy of the information submitted or paid in Exhibit 22.

124. ADMITTED.

125. DENIED.

126. PCCA ADMITS that the numbers alleged herein are correct, but DENIES the allegation about generating a "spread" and the remaining allegations of this paragraph.

127. PCCA ADMITS that it actively marketed this product, but DENIES the remaining allegations and characterizations.

128. PCCA DENIES the first sentence, but agrees that the entire email chain, taken in context, speaks for itself.

129. DENIED.

130. PCCA agrees that the entire email chain, taken in context, speaks for itself, but DENIES the "potentially harmful" averment and the remainder of the allegations of this paragraph. PCCA would remind the Court that compound medications are provided by *prescriptions* from physicians. Just as they sometimes prescribe traditional medications on an "off-label" basis, some physicians also write scripts for compounds that include larger than average concentrations of some active ingredients, including fluticasone propionate. PCCA assumes that the prescribing physicians would be acutely aware of their obligations under the Hippocratic Oath.

131. ADMITTED that the email documents, taken in context, speak for themselves.

132. PCCA DENIES the "inflation" characterization, but admits that this product was a top seller by 2015.

133. PCCA DENIES the allegation of "inflated AWP spreads" and does not have sufficient knowledge or information to either admit or deny the remaining allegations about what was, or was not, submitted to TRICARE.

134. PCCA does not have sufficient information or knowledge to either admit or deny this allegation.

135. ADMITTED that PCCA "promoted" resveratrol, and, indeed all, of its products.

136. PCCA does not have sufficient information or knowledge to either admit or deny this allegation.

137. PCCA ADMITS it sold resveratrol for under $2 per gram, but with the qualification or explanation that prices for such products vary widely based on the volume of the customer's purchase. For example, the price per gram for a one-gram package is significantly higher than 1/1000th of the price of a kilo of the product. PCCA began selling resveratrol in 2009 in a 5 g size. It sold the product for $960/5 g or $192/gram. In 2014, PCCA continued to sell the 5 g size, but customers began requesting larger sizes (including a 1 kg size). Naturally a 1 kg size will get better pricing than a 5 g quantity and PCCA sold the 1 kg on average at $1.69/gram. However, PCCA did not adjust AWP at that time.

138. PCCA ADMITS that the March 9, 2012 number, and the January 2015 number are accurate. The remainder of the allegations in this paragraph are DENIED.

139. DENIED.

140. As a general matter, PCCA was not privy to what its customers billed or what ESI and/or TRICARE approved and paid. Therefore, it is without knowledge or information to either admit or deny this allegation.

141. First sentence in DENIED. Second and third sentences are ADMITTED. These tiers existed before the implementation of D.0 in January 2012 and continued thereafter.

142. ADMITTED.

143. Word "rewarded" is DENIED. ADMITTED that PCCA sponsored "WOW" trips which included both educational seminars and some "fun-filled" activities. Also, the quoted document speaks for itself.

144. ADMITTED.

145. ADMITTED.

146. PCCA DENIES the "inducement" allegation, but certainly ADMITS that from time-to-time WOW trips were utilized as a marketing tool to recognize good customers. However, nothing about them was related to TRICARE claims. The quoted document speaks for itself.

147. ADMITTED, with the caveat or explanation that the quoted document speaks for itself.

148. ADMITTED.

149. The allegation of a "negotiating tool" is DENIED, but PCCA ADMITS that the exhibit is accurately quoted and speaks for itself.

150. DENIED.

151. DENIED.

152. DENIED.

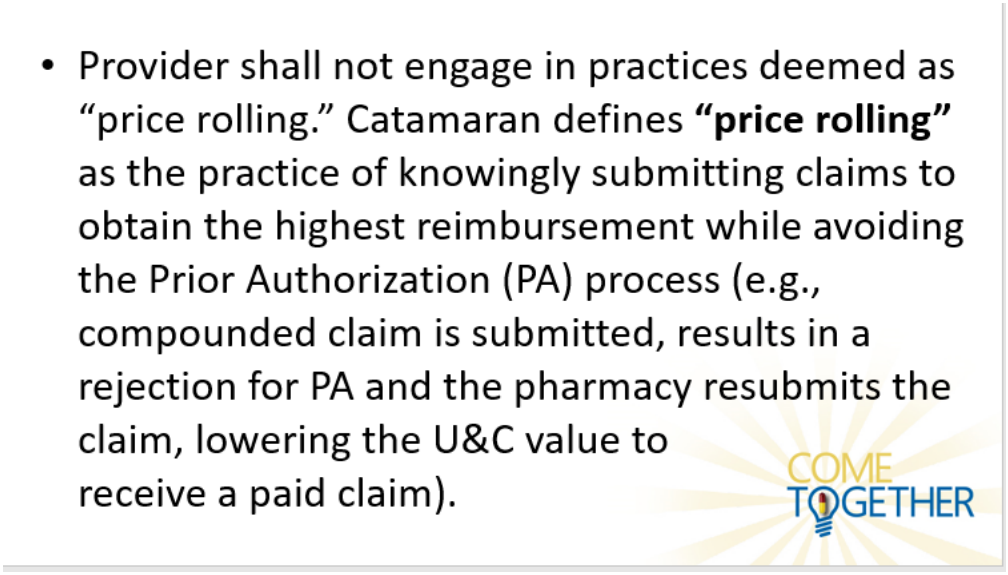
153. DENIED.

154. ADMITTED that the quotes are correct, but DENIED the allegation about "concern" over a comparison between a pharmacy's acquisition cost and the published AWP for the same ingredients. Also DENIED that this example had anything to do with a TRICARE claim.

155. The quotations from this email are ADMITTED. The remaining allegations are DENIED.

156. ADMITTED but with caveat that quotes are out of context and incomplete. The quote comes from a single seminar on July 26, 2014 at which there were a limited number of PCCA members/customers. PCCA's goal in educational programs of this nature was to try to make sure that for all insurance or third party/PBM audits, the customers needed to comply with information that tracked to the original "presentment" criteria, as laid out in D.0. These call for reporting of the total aggregate acquisition costs of all ingredients, but not for ingredient-by-

ingredient pricing/cost information. Indeed, the following Power Point slide from similar presentation appears immediately after a slide regarding what information is generally required when submitting claim to government payors, like Medicare and Medicaid:



PCCA did recommend that in the context of an audit, customers not divulge private acquisition costs for any single ingredient in a compound, but did NOT recommend that the pharmacies withhold the sum total of the "ingredient costs" for all ingredients in the completed compound or withhold any information that either ESI or TRICARE required as part of the claims presentment process.

157. DENIED as phrased. The advice to the seminar attendants was to provide information to the auditors that corresponded with what was required by D.0 submissions and the PBM's provider guidelines.

158. PCCA ADMITS that it had the growth and gross revenue figures alleged herein, but denies that it was because of its "AWP pricing practices." In fact, PCCA did not get one dollar of the taxpayers' money. The explosive growth in all compounding business during this period was attributable to the fact that now, because patients had a means of obtaining third party

reimbursement, doctors were prescribing more compounded medications and patients were receiving more.

159. PCCA ADMITS that the quotations are accurate but DENIES the remainder of the allegations of this paragraph. The "victory" described was the ability of patients to obtain the continuing benefits from compounded medications.

160. ADMITTED.

161. ADMITTED.

162. ADMITTED.

163. ADMITTED.

164. DENIED. The only thing that seemed to be really "material" to TRICARE is that servicemembers and veterans could obtain the enormous benefits of treatment with compounded medications. Indeed, the 2014 GAO report of which this Court has already taken judicial notice establishes as an "adjudicative fact" that TRICARE's "generous" payments of these claims was made, primarily, in violation of its own regulations.

165. The cited government regulations speak for themselves and should have been binding on TRICARE itself, ESI, and the pharmacy providers. They had no applicability to ingredient suppliers like PCCA. At this point in time, because PCCA has not been provided with adequate claims data and other documents that would show what, in fact, was "material" to both ESI and TRICARE, PCCA is without knowledge or information to either admit or deny the last sentence of this paragraph.

166. DENIED as phrased. The cited regulations speak for themselves.

167. The cited regulations speak for themselves.

168. The cited regulations speak for themselves. Because PCCA has not been provided with a copy of the contract referenced in the last sentence it does not have the knowledge or

information necessary to either admit or deny it. At the risk of repetition for clarity's sake, PCCA did NOT contract with TRICARE or its agent ESI, or, indeed, any other PBM or third-party payor.

169. The cited regulations speak for themselves. Pleading further, PCCA would show the Court that the regulations in fact do not provide for the reimbursement of compound prescription claims and, therefore, just as the GAO found in 2014, ESI and TRICARE paid these claims in a knowingly violation of or deviation from its regulatory authority.

170. ADMITTED.

171. PCCA is without knowledge or information to either admit or deny just why TRICARE finally took this action.

172. ADMITTED.

173. DENIED.

174. PCCA certainly ADMITS that the United States made a $22.5 million dollar settlement with its competitors Fagron and Freedom Pharmaceuticals (which Fagron acquired in 2013), as referenced in the Justice Department press release regarding same. However, it DENIES that this out of court settlement was prompted by any "grossly inflated AWPs." Indeed, Relator Hueseman's original Complaint, Doc. 1, details numerous factual delicts of Fagron, its subsidiaries and affiliates and the other defendants who were released as a result of that settlement, more likely than not, prompted the settlement.

175. The first sentence is ADMITTED. The second is DENIED.

176. PCCA ADMITS that the cited statute contains the quoted language. But it DENIES the remaining allegations of this paragraph.

177. PCCA ADMITS that this language is contained in the ESI Provider Manual for 2013. There are also many other, more pertinent, and relevant provisions in this manual. PCCA will bring same to the Court's attention in the proper time and procedural posture.

178. Although PCCA certainly hopes that the United States scrupulously enforces the law, including AKS, and expects that has probably excluded or suspended providers who violate the law, it must DENY the allegation about how "regularly" such enforcement is. Additionally, as noted elsewhere, PCCA is not a "provider." We will await the Government's proof of this allegation.

179. DENIED.

FIRST CAUSE OF ACTION

(False Claims Act: Causing False or Fraudulent Claims) (31 U.S.C. § 3729(a)(1)(A))

180. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

181. DENIED.

182. DENIED.

183. DENIED.

184. PCCA DENIES that the United States suffered any "actual damages" as a result of its behavior and that it is entitled to any relief in this case.

SECOND CAUSE OF ACTION

(False Claims Act: False Statements Material to False Claims) (31 U.S.C. § 3729(a)(1)(B))

185. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

186. DENIED.

187. DENIED.

188. DENIED.

189. DENIED.

THIRD CAUSE OF ACTION

(Payment by Mistake)

190. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

191. PCCA ADMITS that the United States purports to make a claim under the federal common law, but DENIES the remaining allegations in this paragraph.

192. DENIED. Pleading further, PCCA reiterates (a) that it "presented" no claim whatsoever to the ESI or TRICARE or (b) "benefitted" by receiving one dollar of the taxpayers' money.

FOURTH CAUSE OF ACTION

(Unjust Enrichment)

193. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

194. DENIED.

195. DENIED.

196. DENIED.

FIFTH CAUSE OF ACTION

(Common Law Fraud)

197. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

198. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

199. DENIED.

200. DENIED.

201. DENIED.

PRAYER FOR RELIEF

202. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

203. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

204. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

205. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

206. This allegation concerns law and procedure and is not a "factual" averment for which an answer either admitting or denying is appropriate or required under Rule 8(b).

Defendant PCCA's Affirmative Defenses

~~**FIRST AFFIRMATIVE DEFENSE – FAILURE TO STATE A CLAIM.**~~

~~Pursuant to Rule 8(b) Defendant PCCA maintains its previously asserted affirmative defense that both the legal and factual averments of the Complaint in Intervention do not state a cognizable cause of action with regard to all of the causes of action asserted in this Complaint. PCCA is mindful, of course, that this Court has held that – assuming the facts are accepted as true – which the Court was obliged to do in the Rule 12(b)(6) context, but which the Jury is *not* required to do, the Complaint asserts "plausible" causes of action. Doc. 109. PCCA anticipates, however, that, after discovery it will become clear in a different procedural context, i.e., a Rule 56 motion, that the Government cannot really prove one or more of the elements for each cause of action asserted. Therefore, with respect, this defense is reiterated and maintained.~~

SECOND AFFIRMATIVE DEFENSE – CREDIT OR OFFSET.

PCCA is entitled to a credit or offset for the $22.05 million that the Government obtained via its settlement with Fagron, as well as for all funds recouped from any pharmacy that actually submitted a false or fraudulent claim.

~~**THIRD AFFIRMATIVE DEFENSE – "BUT FOR" CAUSATION.**~~

~~PCCA reurges its previously asserted argument that all of the causes of action asserted against it require "but for" causation, which the Government simply cannot prove.~~

~~**FOURTH AFFIRMATIVE DEFENSE – SUPERCEDING/INTERVENING CAUSES.**~~

~~PCCA would show that the combined causative conduct of multiple other parties, to wit – TRICARE itself, ESI, other suppliers of ingredients used in compounded medications, and the pharmacies who submitted claims that the Government now contends were false or fraudulent rises to the level that nothing that PCCA did, or failed to do, could constitute a "substantial factor" in either (a) the submission of the claims in issue, and/or (b) the approval and payment of same. With~~

~~regard to the statutory causes of action, this defense is not a claim of "comparative fault" but rather an assertion that, because of the conduct of these parties, PCCA's alleged misdeeds, even if completely true (which is disputed) could not be a "substantial factor."~~

~~**FIFTH AFFIRMATIVE DEFENSE – "ABSENCE OF DAMAGES."**~~

~~PCCA would show that the Government is not entitled to recover money damages, under any asserted cause of action, for what it has pled to be a payment made as a result of its own "mistake."~~

~~**SIXTH AFFIRMATIVE DEFENSE – FAILURE TO MITIGATE DAMAGES.**~~

~~Although it appears that this common law defense may not be available *vis-à-vis* the *statutory* causes of action, it is asserted as to the federal common law causes of action.~~

~~**SEVENTH AFFIRMATIVE DEFENSE – GOOD FAITH/MEETING COMPETITION.**~~

~~Fair and vigorous competition is important under the law. Indeed, although there is no explicit parallel in either the FCA or KSA, it is significant that "meeting competition" is a recognized defense to a "price" based violation of the Robinson-Patman amendments to the Clayton Act. PCCA's actions in this case were all done in the context of a good faith effort to "meet competition." PCCA also realizes that, technically speaking, "good faith" is not necessarily an affirmative defense, at least with regard to the two statutory causes of action. Rather, as the Fifth Circuit has noted in several cases, it is something that negates scienter in an FCA case. In any event, as a matter of providing "fair notice" of the defense position in this case, with regard to all causes of action asserted, PCCA reiterates that its conduct was all done in good faith to meet the competitive situation in the compounding pharmacy suppliers' market.~~

~~**EIGHTH AFFIRMATIVE DEFENSE – REWARDS PROGRAM IS NOT PROHIBITED REMUNERATION.**~~

~~The Government's Complaint in Partial Intervention has not alleged facts that would satisfy the definition of remuneration under the Anti-Kickback Statute or the type of activity the Anti-Kickback Statute was designed to prevent. The alleged reward program was available to all customers regardless if the customer sought reimbursement or not from any federal healthcare program or the item that was purchased. Thus, there is no nexus between that program and the claims presentments in issue in this case.~~

NINTH AFFIRMATIVE DEFENSE – "EXCESSIVE FINES"/DUE PROCESS.

The Government seeks both compensatory damages and punitive damages in the form of treble damages and statutory penalties. The combination of treble damages and statutory penalty damages could reach a level that is unconstitutional. As such, PCCA conditionally pleads that the punitive aspect of any damages awarded violates both the Eighth Amendment's prohibition against Excessive Fines and the Due Process clause of the Fifth Amendment.

~~**TENTH AFFIRMATIVE DEFENSE – "LEARNED INTERMEDIARY."**~~

~~To the extent that the Government's claims in this case are based in any measure on the "efficacy" *vel non* of the compounded medications utilized in the asserted claims, PCCA would show that all such medications were compounded to the specifications laid out in *prescriptions* by licensed *physicians*. Therefore, just as the intervening professional judgment of a doctor is a defense – usually asserted under the "learned intermediary doctrine" – to a products liability case, so, too, is it a valid defense to the claims asserted in this, at least insofar as they are based on "efficacy" or the lack thereof.~~

ELEVENTH AFFIRMATIVE DEFENSE – "STATUTE OF LIMITATIONS"

The statute of limitations for FCA cases (including civil claims brought pursuant to the AKS) is either (1) six years from the date of violation, or (2) three years from the date that the Government knew, or reasonably should have known of the violation, "but in no event more than 10 years after the date on which the violation is committed." 31 U.S.C. § 3731(b). In a "qui tam" case like the one at bar, "relation back" to the Relator's filing date is permitted only "to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person. 31 U.S.C. § 3731(c).

Relator Hueseman's Original Complaint was filed on March 10, 2014. Thus, the three-year period of subsection 3731(b)(2) ran out on March 9, 2017. The Government's Complaint in Partial Intervention was filed on November 1, 2021. [Doc.66]. It specifically alleges that TRICARE made a major change in its reimbursement policies for compounded medications on or about May 1, 2015. Doc. 66 at ¶ 170. The Government's First Supplemental Rule 26 Disclosures claim damages from the "time period January 1, 2012 to May 31, 2015." Thus, it is indisputable that the Complaint in Intervention was filed SIX YEARS AND FIVE MONTHS after the last alleged damages were sustained by the Government.

Here, as in *Aldridge, supra,* the allegations of Relator Hueseman's Original Complaint are far, far different from those of the Government's Complaint in Partial Intervention filed seven and a half years later. "Thus, the upshot of the Government's complaint was 'to fault (Appellants)[PCCA] for conduct different from that' alleged by Aldridge [Hueseman]." *Aldridge, supra.* "Rather than 'clarifying' or 'adding detail' to the relator's initial allegations, the Government's intervening complaint set forth new ones. Those new claims do not relate back under § 3731(c) to the date of Aldridge's [Hueseman's] original complaint." *Id.*

With regard to the alternative avenue around limitations, i.e., "tolling" all that need be said for purposes of this Amended Answer is that the juridical facts are even more "egregious" and "inexcusable" than the ones branded as such by the Fifth Circuit in *Aldridge.*

For these reasons, in this case, as in *Aldridge,* "the FCA's statute of limitations applies to bar the Government's claims against Appellants accruing before . . . , six years prior to when the Government filed its first intervenor complaint, and the damages awarded against Appellants [PCCA] must be ~~remitted~~ [precluded] accordingly." *Id.*

WHEREFORE, PREMISES CONSIDERED, Defendant PCCA prays that upon proper motion or final trial, that Plaintiff United States of America and Relator Peter Hueseman take nothing, that this suit be dismissed with prejudice, and for all other relief to which Defendant is entitled.

Respectfully submitted,

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Certificate of Service

I hereby certify that on December 8, 2023, Defendant's Amended and Restated Answer to Intervenor's Complaint in Partial Intervention was electronically filed with the Clerk of Court using the ECF system, that will send an email notification of such filing to the following counsel of record:

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